



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Siemens Medical Solutions USA, Inc.  
% Ms. Eve Davis  
Regulatory Affairs Specialist  
51 Valley Stream Parkway  
MALVERN PA 19355

January 16, 2015

Re: K142584

Trade/Device Name: iMAR (iterative Metal Artifact Reduction)  
Regulation Number: 21 CFR 892.1750  
Regulation Name: Computed tomography x-ray system  
Regulatory Class: II  
Product Code: JAK  
Dated: December 19, 2014  
Received: December 22, 2014

Dear Ms. Davis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. A faint, large "FDA" watermark is visible in the background behind the signature.

Robert Ochs, Ph.D.  
Acting Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

### Indications for Use

510(k) Number (if known)  
K142584

Device Name  
iMAR (iterative Metal Artifact Reduction)

#### Indications for Use (Describe)

iMAR is Siemens' iterative reconstruction software designed to reduce metal artifacts in CT images. It is a user-selected option, to be used with conventional reconstruction methods (WFBP or iterative reconstruction) on Siemens CT systems.

The amount of metal artifact reduction and corresponding improvement in image quality depends on a number of factors including: composition and size of the metal object, patient size, anatomical location and clinical practice.

It is recommended to perform reconstructions with iMAR enabled, in addition to conventional reconstruction without iMAR.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

#### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 510(k) Summary: iMAR (iterative Metal Artifact Reconstruction) Software

**Company:** Siemens Medical Systems USA, Inc.  
51 Valley Stream Parkway Malvern, PA 19355

**Date Prepared:** December 11, 2014

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

### 1. General Information:

**Importer / Distributor:**

Siemens Medical Solutions USA, Inc. 51 Valley Stream Parkway  
Malvern, PA 19355

**Establishment Registration Number:** 2240869

**Location of Manufacturing Site**

**SIEMENS AG Healthcare**

Siemensstrasse 1  
D-91301 Forchheim, Germany

**Establishment Registration Number:** 3004977335

### 2. Contact Person:

Eve Davis  
Regulatory Affairs Specialist  
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Malvern, PA 19355  
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Email: eve.davis@siemens.com

### 3. Device Name and Classification:

**Trade Name:** iMAR (iterative Metal Artifact Reconstruction) SW

**Classification Name:** Computed Tomography X-Ray System

**Classification Panel:** Radiology

**Classification Regulation:** 21 CFR §892.1750

**Device Class:** Class II

**Product Code:** JAK

### 4. Legally Marketed Predicate Devices:

**Trade Name:** SOMATOM Definition AS Open using MARIS (VA46)

**510(k) #:** K130901

**Clearance Date:** January 2, 2014

**Classification Name:** Computed Tomography X-ray System

**Classification Panel:** Radiology

**CFR Section:** 21 CFR §892.1750

**Device Class:** Class II

**Product Code:** JAK

**Recall Information:** This predicate device has not been the subject of any design related recalls.

**5. Device Description:**

iMAR (Metal Artifact Reconstruction) SW is a new software option, for Siemens Computed Tomography X-ray systems with the Somaris platform operating system. The iMAR software is designed to reduce metal artifacts caused by large and/or dense metal objects in computed tomography images. This submission includes the following device modifications:

- 1) New optional iMAR Software
- 2) A new specific Indication for Use Statement
- 3) Inclusion of a product Claims List

The iMAR software is based on a modification to the predicate device, previously cleared SOMATOM Definition AS Open using "MARIS" (Metal Implant Reduction in Image Space) VA46 (K130901) computed tomography system cleared under Premarket Notification K130901 on 01/02/2014.

The modified subject device the iMAR Software is within the same classification regulation with a specific indication for use from the primary predicate device; however, the intended use and the general Indication for Use Statement for Siemens' Computed Tomography X-ray system remains the same.

We believe these modifications are eligible for the Traditional 510(k) process since it has the same fundamental scientific technology, Intended use and general Indication for Use as the predicate device system. The new specific Indication for Use statement is supported with non-clinical testing. Documentation is provided to support a claim of substantial equivalence to Siemens' primary predicate device the SOMATOM Definition AS Open using MARIS VA46 (K130901).

**6. Indication for Use:**

iMAR is Siemens' iterative reconstruction software designed to reduce metal artifacts in CT images. It is a user-selected option, to be used with conventional reconstruction methods (WFBP or iterative reconstruction) on Siemens CT systems.

The amount of metal artifact reduction and corresponding improvement in image quality depends on a number of factors including: composition and size of the metal object, patient size, anatomical location and clinical practice.

It is recommended to perform reconstructions with iMAR enabled in addition to conventional reconstruction without iMAR.

**7. Summary of Technological Characteristics of the Subject Device as Compared to the Predicate Device:**

The iMAR Software is designed to reduce metal artifacts caused by large and/or dense metal objects in computed tomography images. The primary predicate device, the SOMATOM Definition AS Open using MARIS (VA46), was 510(k) cleared with the MARIS software which also reduces metal artifacts in scanned images. The subject device (iMAR) is comparable in general Computed tomography indication for use, same intended use, design, material, functionality,

technology, energy source and is considered substantially equivalent to the commercially available Siemens' SOMATOM Definition AS Open using MARIS (VA46).

The components of the subject device have many of the same technological characteristics as the components from the predicate device. There are several technological characteristics that differ slightly, as show below. The iMAR Software is designed to reduce metal artifacts caused by large and/or dense metal objects in computed tomography images. The predicate device has the MARIS feature which reduces metal artifact in images.

#### Subject and Predicate Device Compared Technological Characteristics

Property	Subject Device: iMAR	Predicate Device: SOMATOM Definition AS Open using MARIS (VA46)
<b>Physical effects corrected</b>	beam hardening, scatter, undersampling and photon starvation	beam hardening
<b>Corrections applied in</b>	projection domain and image domain	projection domain and image domain
<b>User- controllable settings</b>	pre-defined parameter sets optimized for a range of different clinical situations	5 strength levels

Testing and validation is complete. Test results show that the subject device, the iMAR Software, is comparable to the predicate device and therefore is substantially equivalent.

The modifications of the subject device, the iMAR Software, do not alter the intended use or fundamental scientific technology from the 510(k) cleared predicate device, the SOMATOM Definition AS Open using MARIS (VA46).

#### 8. Performance Testing:

The modifications described in this premarket notification are supported with software verification/validation. Verification and Validation testing of the device was found acceptable to support claims of substantial equivalence. Non-clinical tests (integration and functional), including bench testing were conducted for the iMAR Software during product development. The Risk Analysis was completed and risk control implemented to mitigate identified hazards. The test results show that all of the software specifications have met the acceptance criteria.

Siemens claims conformance to a signed statement of conformance to the following six (6) performance standards: **60601-1; 2005; 60601-2-44; 2009; 60601-1-6; 2006; 14971:2010; 62304 Ed. 1.0 2006, and PS 3.1 – PS3.18.**

Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005 is also included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software.

Evaluation of clinical images was conducted and judged acceptable by a certified radiologist.

**9. General Safety and Effectiveness Concerns:**

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis which is used to identify potential hazards. These potential hazards are controlled during software development, and verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

**10. Conclusion as to Substantial Equivalence:**

The predicate device was cleared based on non-clinical supportive information. The subject device bench testing, Verification and validation testing, and the evaluation of clinical images demonstrate that the iMAR Software performs as intended. The non-clinical test data and evaluation of clinical images demonstrate that the iMAR device performance is comparable to the predicate device that is currently marketed for the same intended use.

In summary Siemens is of the opinion that iMAR does not introduce any new potential safety risk and is substantially equivalent to the MARIS functionality of the predicate device.